restriction to one of the following allegedly independent and distinct inventions characterized by the following Groups I-VIII:

I. Group I, claims 1-9 and 24, drawn to methods of diagnosing bladder cancer in which nucleic acids are detected, classified in class 435, subclass 6;

II. Group II, claims 1-9, 18-19, and 24-25, drawn to a methods of diagnosing bladder cancer in which polypeptides are detected, classified in class 435, subclass 7.1;

III. Group III, claims 10-13 and 22-23 drawn to polynucleotides, classified in class 536, subclass 23.5;

IV. Group IV, claims 14-16, drawn to polypeptides, classified in class 530, subclass 350;

V. Group V, claim 17, drawn to antibodies, classified in class 530, subclass 387.1;

VI. Group VI, claim 20, drawn to methods of treating bladder cancer by administering a compound that inhibits a gene, classified in class 514, subclass 44;

VII. Group VII, claim 20, drawn to methods of treating bladder cancer by administering a compound that inhibits a polypeptide, classified in class 424, subclass 138.1; and

VIII. Group VIII, claim 21, drawn to a gene therapy vehicle, classified in class 435, subclass 320.1.

The Examiner has further restricted to each Group, requiring the election of a single SEQ ID NO., or, if applicable, a pair or group of SEQ ID NOS. encoding a single polypeptide sequence.

The Examiner alleged that the inventions of Groups I, II, VI and VII are patentably distinct methods by virtue of employing different sets of reagents in different process steps.

The Examiner further alleged that the inventions of Groups III, IV, V, and VIII are patentably distinct because they are drawn to chemically and biologically distinct molecules have different structures and functions.

The Examiner asserted at the inventions of Groups I and III, Groups III and VI, Groups VIII and VI, Groups IV and II, Groups IV and VII, Groups V and II, and Groups V and VII are related as product and process of use. Inventions in this relationship can be shown to be distinct if (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product as set our in MPEP §806.05(h). The Examiner alleged that the polynucleotides of Group III and the gene therapy vehicle of Group VIII can both be employed in materially different processes, such as methods of making protein. The Examiner alleges at the polypeptides of Group IV may be employed in a methods of characterizing protein-

protein interactions, and that the antibodies of Group V may be employed in methods of protein purification. For these reasons, the Examiner asserted that these Groups are patentably distinct.

The Examiner alleged that the inventions of Groups III and II, Groups III and VII, Groups VIII and I, Groups VIII and II, Groups VIII and VII, Groups IV and I, Groups IV and VI, Groups V and I, and Groups V and VI are unrelated to each other since it can be shown that they are not disclosed as capable of use together and have different modes of operation, different functions, or different effects as set out in MPEP §§ 806.04 and 808.01.

In response, applicants hereby elect, with traverse, the amended claims of Group I, specifically claims 1-2, 4-7, 9, and 24, as amended, without prejudice to prosecuting the non-elected claims in a divisional application. Please note that claims 3 and 8 have been canceled without prejudice or disclaimer to pursuing these claims in a continuation or divisional application. New claims 26-29 are also elected as being claims directed to the invention of Group I.

The Examiner finds that in claims 1-9, 20 and 24, methods of detecting nucleic acids and polypeptides and methods of treating employing nucleic acids and polypeptides are improperly joined. However, applicants note that the claims deal only with polynucleotides and not with polypeptides. The term "polypeptide-encoding polynucleotide" refers to polynucleotides only.

Additionally, applicants elect the pair of polynucleotides which are SEQ ID NOS. 56 and 57.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed $55.00 fee for a one-month extension of time and the $18.00 fee for the net addition of two dependent claims, is deemed necessary in connection with the filing of this Amendment in Response to October 2, 2002 Office Action. Accordingly, a check in the amount of $73.00 is enclosed. However, if any other fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231

12/2/02
John P. White Date
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Marked-up Version of Amended Claims

The terms in square brackets have been removed, and the terms underlined have been added.

1. (Amended) A method of diagnosing bladder cancer in a subject which comprises the step of:

determining, in a sample from the subject, the level of expression of at least [one] two polypeptide-encoding polynucleotides, wherein a higher level of expression of the polynucleotides compared to the level of expression of the polynucleotides in a subject free of bladder cancer is indicative of bladder cancer, and wherein the polypeptide-encoding polynucleotides [comprises a polynucleotide] are selected from the group consisting of: [essentially of]

a. the polynucleotides [listed in Tables 3, 4 and 6] having sequences represented by SEQ ID NOS: 57, 56, one of 41 or 42, 45, 61, 48, 51, 47, 55, 58, 43, 44, 53, 49, 60, 59, 52, 46 and 50 ;

b. polynucleotides having sequences that differ from the polynucleotides in (a), without changing the polypeptides encoded thereby; and

c. polynucleotides which are at least 70% homologous to the polynucleotides of (a).

2. (Amended) The method according to claim 1, wherein said determining step includes determining the level of expression of at least [one] two polypeptide-encoding polynucleotides, wherein the polypeptide-encoding polynucleotides [comprises a polynucleotide] are selected from the group consisting of the polynucleotides [listed in Tables 3, 4 and 6] having sequences represented by SEQ ID NOS: 57, 56, one of 41 or 42, 45, 61, 48, 51, 47, 55, 58, 43, 44, 53, 49, 60, 59, 52, 46 and 50 ;

4. (Amended) The method according to claim 1, wherein the [analyzing] determining step includes [the step of] using mRNA from [the] an expressed gene to hybridize to at least [one] two polynucleotides selected from the group consisting of the polynucleotides having [of the] sequences [in Tables 3, 4 and 6] represented by SEQ ID NOS: 57, 56, one of 41 or 42, 45, 61, 48, 51, 47, 55, 58, 43, 44, 53, 49, 60, 59, 52, 46 and 50.

7. (Amended) A method of diagnosis of stageTa in transitional cell carcinoma in a patient which comprises [the step of]:

determining, in a sample from the patient, the level of expression of at least [one] two polypeptide-encoding polynucleotides, wherein a higher level of expression of the polynucleotides compared to the level of expression of the polynucleotides in a patient free of transitional cell carcinoma is indicative of stageTa, and wherein the polypeptide-

encoding polynucleotides [is] are selected [from a polynucleotide selected] from the group consisting of:

a. the polynucleotides [listed in Tables 3, 4 and 6] having sequences represented by SEQ ID NOS: 57, 56, one of 41 or 42, 45, 61, 48, 51, 47, 55, 58, 43, 44, 53, 49, 60, 59, 52, 46 and 50 ;

b. polynucleotides having sequences that differ from the polynucleotides in (a), without changing the polypeptides encoded thereby; and

c. polynucleotides which are at least 70% homologous to the polynucleotides of (a).

9. (Amended) A method of differential diagnosis of stageT1 in transitional cell carcinoma in a patient which comprises [the step of]:

determining, in a sample from the patient, the level of expression of at least [one] two polypeptide -encoding polynucleotides, wherein a higher level of expression of the polynucleotides compared to the level of expression of the polynucleotides in a patient free of transitional cell carcinoma is indicative of stageT1, and wherein the polypeptide -encoding polynucleotides [comprises a polynucleotide] are selected from the group consisting of:

a. the polynucleotides [listed in Tables 3, 4 and 6] having sequences represented by SEQ ID NOS: 57, 56, one of 41 or 42, 45, 61, 48, 51, 47, 55, 58, 43, 44, 53, 49, 60, 59, 52, 46 and 50;

b. polynucleotides having sequences that differ from the polynucleotides in (a), without changing the polypeptides encoded thereby; and

c. polynucleotides which are at least 70% homologous to the polynucleotides of (a).

24. (Amended) The method according to claim[s] 1 [and claims 18], wherein the bladder cancer is transitional cell carcinoma.